Comments of the Independent Regulatory Review Commission

Department of Health Regulation #10-224 (IRRC #3343)

Long-Term Care Nursing Facilities

July 27, 2022

We submit for your consideration the following comments on the proposed rulemaking published in the May 28, 2022 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (RRA) (71 P.S. § 745.5b). Section 5.1(a) of the RRA (71 P.S. § 745.5a(a)) directs the Department of Health (Department) to respond to all comments received from us or any other source.

1. Determining whether the regulation is in the public interest; Protection of the public health, safety, and welfare; Reasonableness; Implementation.

The Department has submitted this proposed regulation as the fourth and final of a series of rulemaking packages which promulgate comprehensive amendments to Subpart C (relating to long-term care facilities):

- Proposed Rulemaking Package #1 (regulation #10-221) was published in the *Pennsylvania Bulletin* on July 31, 2021, and this Commission issued comments on September 29, 2021;
- Proposed Rulemaking Package #2 (regulation #10-222) was published in the *Pennsylvania Bulletin* on October 9, 2021, and this Commission issued comments on December 8, 2021; and
- Proposed Rulemaking Package #3 (regulation #10-223) was published in the *Pennsylvania Bulletin* on March 19, 2022, and this Commission issued comments on May 18, 2022.

As with the previous rulemaking packages, members of the regulated community continue to oppose to the delivery of separate proposed regulations. We include a sampling of the statements made by the regulated community as taken from the submitted comments:

- ". . . this fragmented process has and will continue to create confusion, and make it challenging for [commenters] and the regulated community to have a clear understanding of the impact of the proposed provisions in their totality." [PA Health Care Association (PHCA)]

- "Without view of the comprehensive package, neither the regulated community nor the public can assess the full scope of changes that may be promulgated as final." [LeadingAge PA]
- "We found it quite challenging and cumbersome to review and comment on each package in isolation of the remaining proposed changes." [American Association of Retired Persons – PA Chapter]

We agree with the continuing concerns of the regulated community and question whether the presentation of this regulation as a separate regulation rather than as part of a comprehensive regulatory package is in the public interest and reasonable, and protects the public health, safety, and welfare. We encourage the Department to reevaluate its approach to the promulgation of these rulemakings and consider submitting one comprehensive regulatory package regarding long-term care nursing facilities.

If the Department proceeds with separate regulatory packages, we recommend that the Department deliver each of the individual packages as final regulations on the same day, which would give the regulated community an opportunity to review the separate final regulations at the same time. We want to make clear that doing so is not the equivalent of withdrawing and submitting one comprehensive regulatory package, which would include a public comment period, providing both the regulated community and this Commission an opportunity to provide feedback on the entirety of the Department's proposed changes regarding long-term care nursing facilities.

Further, if the Department proceeds on this course, we suggest that the Department consider issuing an Advance Notice of Final Rulemaking (ANFR) to assist in reaching consensus. Section 2(a) of the RRA states, "To the greatest extent possible, this act is intended to encourage the resolution of objections to a regulation and the reaching of a consensus among the [C]ommission, the standing committees, interested parties and the agency." 71 P.S. § 745.2(a). An ANFR would provide the regulated community with an opportunity to offer input on the entirety of the four regulatory packages prior to the Department's delivery of the final-form versions of the regulations.

Finally, commenters express concern with the Department's statement in the Regulatory Analysis Form (RAF) that the expected effective date of the final-form regulation is upon publication in the *Pennsylvania Bulletin*. They assert that this is not reasonable. One commenter notes that compliance with new regulations takes time to understand the required changes and requires planning to initiate the staffing and budget changes to achieve compliance. The commenter asserts that it is particularly unreasonable to assume that the private-pay long-term care nursing facilities will be able to implement immediately Federal regulations with which they need not currently comply. Commenters are particularly concerned about the implementation timeframe for Section 211.12 (related to nursing services). We ask the Department to address the reasonableness of the implementation timeframe in the final regulation and to explain what alternatives were considered to ease the implementation burden, particularly as relates to nursing services.

2. Determining whether the regulation is in the public interest; Protection of the public health, safety, and welfare; Reasonableness.

The Department explains in the Preamble that the proposed amendments include the elimination of provisions that are duplicative and that conflict with the Federal requirements. While some commenters support this aspect of the proposed regulation, other commenters oppose these changes. One commenter asserts that "the proposed revisions of the regulations reflect a massive and sometimes incomplete or unjustified deferral to the [F]ederal regulations." Commenters note that the existing state regulations had already expanded or improved upon the Federal requirements, which means that the deletion of such provisions would be taking away existing improvements by reverting to the lesser Federal regulations. For any provisions that currently expand upon the Federal requirements and which the Department deletes at final, we ask the Department to address in the Preamble to the final regulation the reasonableness of deferring to the Federal requirements. We further ask the Department to explain how the final regulation protects the public health, safety, and welfare related to deleted provisions which are more protective than Federal requirements. We will consider the Department's responses in order to determine whether the regulation is in the public interest.

Additionally, we note that these proposed regulations address the care of residents of long-term care nursing facilities. People who have a family member in a facility and who are not familiar with these or Federal regulations should be able to access easily the regulations that govern long-term care nursing facilities. In most cases where the Department deletes provisions and defers to Federal regulations, the applicable Federal regulation is not cross-referenced. Without cross-references to the appropriate Federal requirements, individuals may not be able to identify or find the corresponding applicable Federal provisions. For protection of the public health, safety, and welfare, we ask the Department to cross-reference provisions deleted from the final regulation to the appropriate Federal requirements.

Additionally, commenters are concerned that facilities that are solely private pay would not be bound by these requirements since the Federal regulations found at 42 CFR Part 483 establish conditions of participation for the Medicare and/or Medicaid program. We note that 42 CFR § 483.1(b) (related to scope) states:

> The provisions of this part contain the requirements that an institution must meet in order to qualify to participate as a Skilled Nursing Facility in the Medicare program, and as a nursing facility in the Medicaid program. They serve as the basis for survey activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid.

We ask the Department to explain the reasonableness of applying 42 CFR Part 483 to facilities which are not seeking Medicare reimbursement.

CHAPTER 201. APPLICABILITY, DEFINITIONS, OWNERSHIP AND GENERAL OPERATION OF LONG-TERM CARE NURSING FACILITIES

OWNERSHIP AND MANAGEMENT

3. Section 201.18. Management. – Protection of the public health, safety, and welfare; Clarity; Need; Reasonableness; Implementation procedures.

Subsection (d.1) provides for requirements to be met in order for facilities with 25 beds or less to share an administrator. Under Paragraph (d.1)(4), one requirement is that the director of nursing services has "adequate knowledge and experience" to compensate for the time the administrator is not in the building. What standards will determine "adequate knowledge and experience?" We ask the Department to clarify this provision in order to establish enforceable standards that can be predicted by the regulated community.

Subsection (d.2) requires the administrator's schedule to be publicly posted in the facility. What are the expectations for the posting, updating, and accuracy of the schedule? Is it to be posted daily or weekly? Can it be a "normal" or "anticipated" schedule? If the administrator gets sick, must the schedule be updated? We ask the Department to clarify the standards for implementation of this provision in the final regulation.

Subsection (e) provides for the administrator's responsibilities. Under Subsection (e)(2.1), the administrator is responsible for ensuring "satisfactory" housekeeping in the facility and maintenance of the building and grounds. What standards will determine "satisfactory" housekeeping? We ask the Department to clarify this provision in order to establish enforceable standards that can be predicted by the regulated community.

The Department proposes to amend Subsection (f) related to written records of residents' personal possessions received or deposited with the facility, removing a requirement to maintain a written record of residents' "funds" and "expenditures and disbursements made on behalf of the resident." Commenters object to these deletions. One commenter states that existing regulations are more protective than Federal regulations. Another commenter notes that this provision requires a record of all that has been done with those funds to be available at all times to residents, while the Federal requirement provides for financial records to be available to residents through quarterly statements. We ask the Department to explain the need for and reasonableness of residents only receiving quarterly statements. Also, we ask the Department to explain how the final regulation protects the public health, safety, and welfare related to records of residents' personal possessions.

Subsection (h) is amended to address the length of time that a facility has to provide a resident with cash or a check. The provision states, "The facility shall provide cash, if requested, within [one] day of the request or a check, if requested, within [three] days of the request." Existing language requires that the facility provide residents with access to their money within three bank business days of the request. The Department states in the Preamble that it proposes no amendment to the existing requirement that a check be provided, if requested, within three days.

We note that the Department made a slight modification in removing the existing language of "bank business" to describe how to count the days. We ask the Department to clarify how the days are to be counted for implementation of the final regulation.

4. Section 201.19. Personnel records. – Reasonableness.

This section addresses the information to be kept in an employee's personnel records. Paragraph (8) requires criminal history information to be included in these records. Paragraph (9) would require, in the event of a conviction prior to or following employment, a determination by the facility of an employee's suitability for initial or continued employment in the position to which the employee is assigned. What information does the Department anticipate being included in an employee's personnel records related to a conviction? We ask the Department to explain the reasonableness of the requirements related to personnel records in the final regulation. We also ask the Department to explain whether these requirements are consistent with the Commonwealth Court's ruling in *Peake v. Commonwealth of PA*, 132 A.3d 506 (Pa. Cmwlth. 2015) regarding individuals with criminal convictions.

5. Section 201.20. Staff development. – Protection of the public health, safety, and welfare.

The Department proposes in Subsection (b) to delete the following requirement: "The orientation shall include training on the prevention of resident abuse and the reporting of the abuse." A commenter opposes this amendment, stating that although the Federal training requirements include this topic, the Federal regulations do not require it to be taught at an orientation. The commenter asserts that "training on the prevention and reporting of abuse (and facility-specific procedures) are cardinal areas which must be taught to staff immediately upon starting to work in a facility." We ask the Department to explain how the final regulation protects the public health, safety, and welfare related to training on the prevention and reporting of abuse.

6. Section 201.21. Use of outside resources. – Protection of the public health, safety, and welfare; Clarity; Implementation.

The Department proposes to delete Subsections (a) – (c) in order to eliminate duplication and to avoid conflict with the Federal requirements. Subsection (a) states, "The facility is responsible for insuring that personnel and services provided by outside resources meet all necessary licensure and certification requirements, including those of the Bureau of Professional and Occupational Affairs in the Department of State, as well as requirements of this subpart." Subsection (c) states, "The responsibilities, functions and objectives and the terms of agreement, including financial arrangements and charges of the outside resource shall be delineated in writing and signed and dated by an authorized representative of the facility and the person or agency providing the service."

Several commenters strongly object to this proposal. One commenter asserts that Subsections (a) and (c) are not addressed by the Federal provision, which applies to a "qualified professional person." The commenter asserts that if the Federal provision does not include a certified nurse aide, then current Subsection (a) is needed to require the facility to ensure that such personnel

meet all necessary licensure and certification requirements. The commenter further asserts that Subsection (c) should also be retained since it is broader than the Federal provision. The commenter explains that with the proliferation of service provision by related entities, written records, including the financial arrangements and charges of the outside source, are especially important. We ask the Department to explain how deletion of these subsections protects the public health, safety, and welfare related to a certified nurse aid and written records.

Subsection (e) adds a provision that, if a facility acquires employees from outside resources, the facility shall obtain confirmation from the outside resource that the employees are free from the communicable diseases and conditions listed in Section 27.155 (relating to restrictions on health care practitioners) and are physically able to perform their assigned duties. A commenter notes that the qualification of "physically able to perform their assigned duties" is ambiguous and may lead to challenges under the Americans with Disabilities Act. We ask the Department to clarify in the final regulation how the requirement related to evaluating whether a person is physically able to perform their assigned duties is to be implemented.

7. Section 201.24. Admission policy. – Protection of the public health, safety, and welfare; Need; Reasonableness.

The Department proposes to delete Subsection (a) which includes the following provision: "The resident is not required to name a responsible person if the resident is capable of managing the resident's own affairs." Several commenters disagree with the deletion of this provision. One commenter states that residents should be free to choose whether or not they want to designate a representative. Another commenter states that this protection does not appear in the Federal regulations and is an important protection for residents who have capacity to make decisions. We ask the Department to explain the need for deleting this provision, and how the final regulation protects the public health, safety, and welfare of residents capable of managing their own affairs.

In order to eliminate duplication and avoid conflict with Federal requirements, the Department proposes to delete Subsection (b) which states, "A facility may not obtain from or on behalf of residents a release from liabilities or duties imposed by law or this subpart except as part of formal settlement in litigation." Several commenters object to the removal of this provision, stating that the Federal provision only covers liability for losses of personal property, not other types of liability or duties under the licensing regulations. Would facilities be able to obtain a release from other types of liabilities if the Department deletes this provision? We ask the Department to explain how this provision in the final regulation is reasonable and protects the public health, safety, and welfare related to liabilities other than liability for loss of personal property.

Proposed Subsection (f) requires the coordination of introductions, orientation, and discussions, under Subsection (e), to occur within two hours of a resident's admission. We share commenters' concern with the need not to overwhelm a resident during this time of transition. Is this timeframe reasonable considering that an individual may be coming directly from a hospital or have other serious health conditions? We ask the Department to explain the reasonableness of the timeframe related to the coordination of introductions, orientation, and discussions.

8. Section 201.25. [Discharge policy] (Reserved). – Protection of the public health, safety, and welfare.

The Department proposes to delete this section to eliminate duplication and avoid conflict with Federal requirements. The provision states, "There shall be a centralized coordinated discharge plan for each resident to ensure that the resident has a program of continuing care after discharge from the facility. The discharge plan shall be in accordance with each resident's needs." Several commenters object to the removal of this provision. One commenter explains that discharges are one of the most frequent resident rights problem areas. The commenter notes that the Federal provision focuses on the discharge planning process rather than the plan itself. Do the Federal requirements address a centralized coordinated discharge plan for each resident as required by existing regulation? We ask the Department to explain how the final regulation protects the public health, safety, and welfare of residents regarding discharge plans.

9. Section 201.29. Resident rights. – Protection of the public health, safety, and welfare; Clarity; Reasonableness.

Several commenters oppose the deletion of provisions from this section relating to resident rights. A commenter states that laypeople do not understand the interplay between state and Federal law, and that most people would look to state regulations to determine their rights as a resident of a Pennsylvania-based long-term care nursing facility. The commenter requests that state regulations should either spell out all rights, or, at a minimum, refer people to the Federal source for the rights. We ask the Department to explain how the final regulation protects the public health, safety, and welfare in relation to making clear resident rights.

The Department proposes to delete Subsection (d) to eliminate duplication and avoid conflict with Federal regulations. Subsection (d) states, "The staff of the facility shall be trained and involved in the implementation of the policies and procedures." Commenters disagree that the provisions are not duplicative of Federal requirements. A commenter asserts that while the Federal provision requires that staff be educated on residents' rights and care requirements, the language that would be deleted requires that staff be trained and involved in the implementation of the **facility's policies and procedures *regarding*** the rights and responsibilities of residents. [Emphasis added.] We ask the Department to clarify whether the existing regulation requires more involvement of staff in policies and procedures than the Federal regulation, and, if so, how the final regulation protects the public health, safety, and welfare by lessening staff involvement.

To eliminate duplication and avoid conflict with Federal requirements, the Department proposes to delete existing Subsection (e) which states,

> The resident or if the resident is not competent, the resident's responsible person, shall be informed verbally and in writing prior to, or at the time of admission, of services available in the facility and of charges covered and not covered by the per diem rate of the facility. If changes in the charges occur during the resident's stay, **the resident shall be advised verbally and in writing reasonably in advance of the change. ''Reasonably in advance'' shall be interpreted to be 30 days unless circumstances dictate otherwise.** If a facility requires a security deposit, the written procedure or contract that is given to the resident or resident's

> responsible person shall indicate how the deposit will be used and the terms for the return of the money. **A security deposit is not permitted for a resident receiving Medical Assistance (MA)**. [Emphasis added.]

Commenters oppose the complete deletion of this provision. One commenter notes that the Federal regulation only requires facilities to inform a resident before changes in charges, without requiring the resident to be informed verbally and in writing. The commenter also notes that the Federal regulations only address changes due to charges not being covered by Medicare or MA. The commenter further opposes the removal of the requirement of at least 30 days advance notice. Another commenter states that the explicit prohibition against security deposits from residents receiving MA does not appear in the Federal requirement referenced by the Department. We ask the Department to explain how the deletion of these provisions related to notice and security deposits are reasonable and protect the public health, safety, and welfare.

The Department proposes to delete from Subsection (g) the following sentence: "Unless the discharge is initiated by the resident or resident's responsible person, the facility is responsible to assure that appropriate arrangements are made for a safe and orderly transfer and that the resident is transferred to an appropriate place that is capable of meeting the resident's needs." Commenters oppose this deletion, emphasizing the protection afforded by the requirement that "the resident is transferred to an appropriate place that is capable of meeting the resident's needs." One commenter asserts that while the transfer/discharge Federal regulation cited in the Preamble addresses the situation where a resident is transferred to another nursing facility, the Federal regulation does not address transfers to other settings. The commenter explains that the language existing in Subsection (g) is the clearest protection for residents of long-term care nursing facilities against being transferred to non-nursing facility settings where their needs will not be met. How will the final regulation protect residents from transfers to settings where their needs cannot be met? We ask the Department to explain the reasonableness of removing this provision and how the final regulation protects the public health, safety, and welfare related to transfers.

To eliminate duplication and avoid conflict with Federal regulations, the Department proposes to delete Subsection (i) which states:

> The resident shall be **encouraged and assisted** throughout the period of stay to exercise rights as a resident and as a citizen and may voice grievances and recommend changes in policies and services to the facility staff or to outside representatives of the resident's choice. The resident or resident's responsible person shall be made aware of the Department's Hot Line (800) 254-5164, the telephone number of the Long-Term Care Ombudsman Program located within the Local Area Agency on Aging, and **the telephone number of the local Legal Services Program** to which the resident may address grievances. **A facility is required to post this information in a prominent location and in a large print easy to read format**. [Emphasis added.]

Commenters oppose this deletion, stating that the existing language contains several elements which are not present in the analogous Federal regulation, including the requirement that a resident "be encouraged and assisted" to exercise rights as a resident and a citizen. Commenters note further that the Federal regulation does not require that the telephone number of the local

legal services program be provided to residents and posted, nor does it require that the information be physically posted in a prominent location and in large print. One commenter emphasizes that posting this information is important for residents to exercise their rights and contact outside advocates for assistance when their rights are being violated. We ask the Department to explain how the final regulation protects the public health, safety, and welfare without these provisions regarding assistance with and notice for exercising rights.

Subsection (m) states, "The resident rights in this section shall be reflected in the policies and procedures of the facility." The Department states in the Preamble that it proposes to delete Subsection (m) because existing Subsection (a) addresses the requirement that a facility have policies and procedures related to resident rights. A commenter notes, however, that Subsection (a) does not require that a facility's policies and procedures reflect the residents' rights provided for in this section, only that policies regarding rights be developed and adhered to. We ask the Department to explain how deletion of the requirement for a facility's policies and procedures to reflect a resident's rights **as provided for in this section** is reasonable and protects the public health, safety, and welfare. [Emphasis added.]

The Department proposes to delete a portion of Subsection (n) to eliminate duplication and avoid conflict with the Federal requirements. The language to be deleted states, "The facility shall on admission provide a resident or resident's responsible person with a personal copy of the notice. In the case of a resident who cannot read, write or understand English, arrangements shall be made to ensure that this policy is fully communicated to the resident." A commenter opposes this deletion, stating that "residents must be provided a copy of their rights and facilities must make accommodations for [Limited English Proficiency] or low-literacy individuals." We ask the Department to explain how this provision in the final regulation protects the public health, safety, and welfare related to providing notice, particularly to a resident who cannot understand English.

10. Section 201.30. [Access requirements] (Reserved). – Protection of the public health, safety, and welfare; Reasonableness.

The Department proposes to delete this section to eliminate duplication and avoid conflict with Federal regulations. Subsection (a) states,

> The facility may limit access to a resident when the interdisciplinary care team has determined it may be a detriment to the care and well-being of the resident in the facility. The facility may not restrict the right of the resident to have legal representation or to visit with the representatives of the Department of Aging Ombudsman Program. A facility may not question an attorney representing the resident or representatives of the Department, or the Department of Aging Ombudsman Program, as to the reason for visiting or otherwise communicating with the resident.

Subsection (b) states:

> A person entering a facility who has not been invited by a resident or a resident's responsible persons shall promptly advise the administrator or other available agent of the facility of that person's presence. The person may not enter the

> living area of a resident without identifying himself to the resident and without receiving the resident's permission to enter.

Several commenters oppose these deletions. Related to Subsection (a), a commenter notes that while the Federal regulations specify the resident's right to visitors, this provision provides more detail to prohibit the facility from interfering with access by others. Another commenter emphasizes that the existing prohibition on the facility questioning an attorney, ombudsman staff, or agency representatives about the reason for visiting a resident is not included in the Federal regulations. Related to Subsection (b), a commenter states that the requirement that a person not enter the living area of a resident without identifying themselves to the resident and receiving permission to enter is not included in the Federal regulations. We ask the Department to explain the reasonableness of not providing in the final regulation for the protection of a resident's right to visitors and control over who enters the living area, and how the final regulation protects the public health, safety, and welfare related to a resident's right to visitors and control over who enters the living area.

11. Section 201.31. [Transfer agreement] (Reserved). – Protection of the public health, safety, and welfare; Reasonableness.

The Department proposes to delete this section to eliminate duplication and avoid conflict with the Federal requirements. Subsection (a) states,

> The facility shall have in effect a transfer agreement with one or more hospitals, located reasonably close by, which provides the basis for effective working arrangements between the two health care facilities. Under the agreement, inpatient hospital care or other hospital services shall be promptly available to the facility's residents when needed.

Subsection (b) states,

> A transfer agreement between a hospital and a facility shall be in writing and specifically provide for the exchange of medical and other information necessary to the appropriate care and treatment of the residents to be transferred. The agreement shall further provide for the transfer of residents' personal effects, particularly money and valuables, as well as the transfer of information related to these items when necessary.

Commenters object to the deletion of this section. One commenter explains that the Federal regulations provide that a nursing facility shall be considered to have a transfer agreement in effect if it attempts in good faith to enter an agreement with a hospital sufficiently close to make transfer feasible. The commenter asserts that it is unacceptable for a nursing facility to lack an agreement permitting it to transfer its residents for hospital care when needed, even if the nursing facility has tried in good faith but failed to obtain such an agreement. The commenter argues that the current provision, which requires there to be a transfer agreement without exception, should be retained in order to protect residents of long-term care nursing facilities. If these provisions are removed from the final regulation, we ask the Department to explain how the final regulation will protect the public health, safety, and welfare in the event of the need to transfer a resident to a hospital without a transfer agreement in effect.

CHAPTER 207. HOUSEKEEPING AND MAINTENANCE STANDARDS FOR LONG-TERM CARE NURSING FACILITIES

HOUSEKEEPING AND MAINTENANCE

12. Section 207.2. [Administrator's responsibility] (Reserved). – Protection of the public health, safety, and welfare; Reasonableness.

The Department states in the Preamble that it proposes to delete Subsection (b) as this provision is "outdated." Subsection (b) states, "Nursing personnel may not be assigned housekeeping duties that are normally assigned to housekeeping personnel." The Preamble states, "In recent years, there has been a shift in the long-term care nursing environment to providing residents with a more homelike environment. Residents being cared for at home would not typically have services provided by multiple people. Prohibiting nursing services personnel from performing any housekeeping duties can contribute to residents feeling as though they are institutionalized regardless of what their environment looks like." Commenters oppose this deletion. A commenter states that "it is not clear how having nursing personnel performing housekeeping tasks would make an environment more homelike. Nursing personnel, who are often understaffed relative to residents' nursing needs, are needed to provide nursing care and should not be diverted to performing housekeeping tasks." Given the numerous comments received on the existing staffing shortage (addressed in Comment #18), we, too, question the reasonableness of expanding the duties of nursing personnel to include housekeeping duties. We ask the Department to explain how adding housekeeping duties to nursing personnel in the final regulation is reasonable and protects the public health, safety, and welfare.

CHAPTER 209. FIRE PROTECTION AND SAFETY PROGRAMS FOR LONG-TERM CARE NURSING FACILITIES

FIRE PROTECTION AND SAFETY

13. Section 209.3. [Smoking] (Reserved). – Protection of the public health, safety, and welfare.

The Department proposes to delete this section related to smoking to eliminate duplication and avoid conflict with Federal requirements. Commenters object to the proposed deletion of this section because there are several aspects of the existing language which are not included in the Federal regulations, including the requirement in Subsection (a) that smoking policies be posted in a conspicuous place and legible format, and the requirement in Subsection (c) that adequate supervision while smoking be provided for residents who need it. We ask the Department to explain how the final regulation protects the public health, safety, and welfare by not providing requirements related to the posting of smoking policies and a requirement for adequate supervision for residents while smoking.

CHAPTER 211. PROGRAM STANDARDS FOR LONG-TERM CARE NURSING FACILITIES

14. Section 211.2. Medical director. – Protection of the public health, safety, and welfare; Clarity; Implementation.

While commenters generally support the changes to this section, some commenters express concerns related to the Department's proposal to delete a portion of Subsection (c). The Department proposes to delete a provision which states that a medical director may "serve on a full- or part-time basis depending on the needs of the residents and the facility." Commenters raise concerns that the Federal regulation permits a medical director to serve on a consultant basis and does not include the provision requiring the consideration of resident and facility needs in deciding the level of medical director presence. The commenter asserts that the existing provision is not duplicative of the Federal requirement, and, that by deferring to the Federal provision, the Department would lower the standard for medical director coverage in Pennsylvania. We ask the Department to explain how permitting a medical director to serve on a consultant basis protects the public health, safety, and welfare, particularly without the qualifying provision that the needs of the residents and facility serve as the basis for the amount of time that a medical director is present.

Further, we have two questions related to the new annual training requirement under Subsection (c) which requires that a medical director shall complete at least four hours annually of continuing medical education. How will this provision be implemented? For example, who will monitor whether the training is completed? We ask the Department to clarify in the final regulation how this training provision will be implemented and monitored for compliance.

15. Section 211.3. Verbal and telephone orders. – Need; Reasonableness.

The Department is proposing to merge portions of existing Subsections (b) and (c) to require verbal and telephone orders for care, treatment, or medication to be dated and countersigned with the original signature of the physician or physician's delegee within 48 hours of receipt of the order, whereas currently only orders for medications must be dated and countersigned within 48 hours. The current timeframe for orders for care and treatment to be dated and countersigned with the original signature of the physician or physician's delegee is seven days. Commenters are concerned that this change will be challenging for many long-term care nursing facilities and may be unreasonable. The Department states in the Preamble that it is imperative that orders be signed within 48 hours to ensure that the orders are correct, especially in cases where the medical issue that is being addressed is urgent. While we agree regarding the importance of accuracy of orders, we ask the Department to further explain the need for such a seemingly significant change. Is the Department aware of an existing problem that this amendment addresses? Does the Department have data to support the need for this change? We ask the Department to explain the reasonableness of the timeframe in which a signature must be obtained for verbal and telephone orders in the final regulation.

16. Section 211.6. Dietary services. – Protection of public health, safety, and welfare; Need.

The Department proposes to delete Subsection (b), which currently requires there to be at least three days' supply of food available in storage in the facility at all times. The Department states in the Preamble, "Requiring a facility to have food on hand for a specific number of days could result in a cost and waste to the facility. Instead, facilities should utilize the emergency plan developed." A commenter disagrees, asserting that the existing provision is not wasteful, and that it would be short-sighted to remove a minimally protective requirement for that reason. What are the minimum number of days' supply of food available in storage in the facility provided for in an emergency plan? We ask the Department to explain the need for and reasonableness of this proposal in the Preamble to the final regulation. Also, we ask the Department to explain how the final regulation protects the public health, safety, and welfare related to having a sufficient food supply available in the facility at all times.

The Department proposes to delete Subsection (d) to eliminate duplication and avoid conflict with Federal requirements. The language to be deleted states, in part, "If consultant dietary services are used, the consultant's visits shall be at appropriate times and of sufficient duration and frequency to provide . . . resident counseling . . . ." A commenter notes that resident counseling is not included in the Federal regulations. Is the Department reducing the standard of care for residents by eliminating this provision? We ask the Department to explain how the final regulation protects the public health, safety, and welfare related to resident counseling by a dietary consultant.

17. Section 211.8. Use of restraints. – Protection of the public health, safety, and welfare; Clarity and lack of ambiguity.

The Department proposes to delete Subsection (c) related to use of restraints, and offers new language in Subsection (c.1). Existing Subsection (c) states:

> Physical restraints shall be removed at least 10 minutes out of every 2 hours during the normal waking hours to allow the resident an opportunity to move and exercise. Except during the usual sleeping hours, the resident's position shall be changed at least every 2 hours. During sleeping hours, the position shall be changed as indicated by the resident's needs.

The Department is deleting the language out of concern that setting forth a requirement in regulation for the removal of restraints for a specified period of time could result in a facility complying only with the minimum standard for removal, rather than considering the health and safety of the particular individual that is being restrained. We note that the deleted language sets finite standards of compliance, whereas proposed Subsection (c.1) states, "If restraints are used, a facility shall ensure that **appropriate** interventions are in place to safely and adequately respond to resident needs." [Emphasis added.] The term "appropriate" is ambiguous and non-regulatory language. Who will determine whether an intervention is appropriate and protective of the residents? We ask the Department to ensure that the final regulation sets standards of compliance related to the use of restraints that are clear, enforceable, lack ambiguity, and protect the public health, safety, and welfare.

18. Section 211.12. Nursing services. – Protection of the public health, safety, and welfare; Need; Reasonableness.

The Department proposes to delete Subsections (b) and (e) to eliminate duplication and avoid conflict with Federal requirements. The language to be deleted in Subsection (b) states, "There shall be a full-time director of nursing services who shall be a qualified licensed registered nurse [(RN)]." The language to be deleted in Subsection (e) states, "The facility shall designate [an RN] who is responsible for overseeing total nursing activities within the facility on each tour of duty each day of the week." A commenter objects to the elimination of these subsections, noting that these requirements are mandatory under Pennsylvania's current regulations but may be waived under the Federal regulations. The commenter further notes that the Federal requirement is only for a licensed nurse, while the existing provision requires an RN. What is the impact if either of these provisions would be waived under the Federal requirements? And what is the impact of having an RN versus a licensed nurse designated as responsible for overseeing total nursing activities within the facility? We ask the Department to explain how the deletion of provisions related to qualifications for a full-time director of nursing services and designating an RN to be responsible for overseeing total nursing activities within a facility protects the public health, safety, and welfare.

Subsection (f.1) proposes minimum staffing ratios for RNs, licensed practical nurses (LPNs), and nurse aides. While some commenters support the proposed staffing ratios, others express concerns, including the following:

- ". . . the result will not be improved quality of care or improved work environment for the staff; instead, it will be the closure or the sale of high-quality nursing facilities." [PHCA]
- ". . . what is being proposed by the [Department] is not reasonable and will be excessively burdensome, if not impossible to achieve . . . . in a small community like ours, there is not a pool of [RNs] or [LPNs] out there waiting to be hired." [Garvey Manor & Our Lady of the Alleghenies Residence]
- "The requirements will compel many providers to either implement or increase the use of agency staffing, which will impact the continuity of care our vulnerable seniors receive." [Concordia Lutheran Ministries]
- "The proposed staffing requirements will place an even greater challenge on providers who are already doing everything they can to recruit staff to fill vacant positions. Staffing challenges are wide spread throughout our state and [continue] to be a huge concern among senior living communities." [Asbury Springhill]
- ". . . the labor shortage is causing long-term care providers to reduce the number of individuals they can serve and halting new admissions to those who need the care the most." [LeadingAge PA]
- "By prescribing standardized nursing ratios, local hiring and staffing patterns aren't able to be taken into consideration. This could disproportionately impact rural and underserved areas where the services are vital to the community." [Warren County Rouse Home]

Furthermore, in new Subsection (i.1), the Department proposes to add a requirement that only direct resident care provided by nursing service personnel be counted towards the total number of hours of general nursing care required under Subsection (i). Subsection (i) currently states, "A minimum number of general nursing care hours shall be provided for each 24-hour period. The total number of hours of general nursing care provided during each shift in each 24-hour period shall, when totaled for the entire facility, be a minimum of 2.7 hours of direct resident care for each resident." The Department has proposed to amend Subsection (i) in the first regulatory package to change the minimum number of direct care resident hours, per day, from 2.7 to 4.1.

Under the new requirement in Subsection (i.1), only direct care provided to residents by RNs, LPNs, and nurse aides would count toward the number of direct care hours under Subsection (i). Subsection (i.1) goes above and beyond the Federal requirements for direct care staffing, as the Federal requirements contemplate that direct care may be provided by additional individuals, including therapists. In response to RAF Question #11, the Department states that the proposed increase in staffing ratios will require:

- The six facilities operated by the Department of Military and Veterans Affairs to employ an additional 166 RNs, 83 LPNs, and 43 nurse aides;
- The 20 county-owned facilities to hire 184 Full Time Equivalent (FTE) RNs but no LPNs, and 539 FTE nurse aides;
- The 594 privately-owned facilities to hire 2,374 FTE RNs, 26 FTE LPNs, and 5,988 FTE nurse aides;
- The 62 facilities that participate only in Medicare to hire 258 FTE RNs, three FTE LPNs, and 659 nurse aides; and
- The three private-pay facilities to hire three FTE RNs, no LPNs, and eight nurse aides.

Given the Department's deferral to Federal requirements throughout this regulation, we ask the Department to explain why the Federal requirements are not sufficient related to who provides direct care. Also, given the level of concern from commenters related to the shortage of qualified staff, we ask the Department to explain the need for and reasonableness of staffing ratios that are more stringent than the Federal regulations.

19. Section 211.15. [Dental services] (Reserved). – Protection of the public health, safety, and welfare.

The Department proposes to delete this section to eliminate duplication and avoid conflict with Federal regulations. Subsection (b) states that a facility "shall make provisions to assure that resident dentures are retained by the resident. Dentures shall be marked for each resident." A commenter states that this provision is an added protection and not duplicative of Federal regulations. Will the deletion of this provision reduce existing protections for residents of long-term care nursing facilities? We ask the Department to explain how the removal of this provision related to dental services protects the public health, safety, and welfare of residents in long-term care nursing facilities.

20. Section 211.16. Social services. – Feasibility; Reasonableness; Implementation.

The Department states in the Preamble that amendments to Subsection (a) require that all facilities have a full-time qualified social worker, regardless of size. While several commenters support this proposal, one commenter is concerned that this new requirement will be difficult for smaller long-term care nursing facilities to meet, particularly if the facility is in a remote/rural area. The Department states in response to RAF Question #11 that an estimated 81 long-term care facilities reported in fiscal year 2019-2020 that they did not have either a full- or part-time social worker. What alternatives did the Department consider to assist rural and small facilities with implementation of this requirement? If the provision is retained in the final regulation, we ask the Department to explain the reasonableness and feasibility of requiring a full-time qualified social worker for all long-term care nursing facilities regardless of size.

21. RAF. – Fiscal impacts.

We appreciate the Department's attempt to estimate the fiscal impacts of the proposed regulation on long-term care nursing facilities. A commenter states that the Department ignores the potential impacts on small businesses. The commenter asserts that the three private-pay facilities are likely to be considered small businesses, and failing to consider the significant impact on these facilities seems to be an egregious omission. Throughout the RAF, the Department states that "any costs to these three facilities are outweighed by the need for consistency in the application of standards to all long-term care nursing facilities, regardless of whether they participate in Medicare or MA." We ask the Department to address the fiscal impacts on small businesses in the Preamble and RAF to the final regulation.

Additionally, a commenter points out that the inflation rate is higher than the five percent inflation rate used in the estimate, and believes that it would be appropriate for the Department to provide updated estimates. We ask the Department to revise the Preamble and RAF to reflect a more current inflation rate for the final regulation.